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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,645	02/25/2002	Hiroyuki Miyachi	219214US0PCT	6387

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EXAMINER

ANDERSON, REBECCA L

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 08/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,645

Applicant(s)

MIYACHI ET AL.

Examiner

Rebecca L Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6 and 9-12 is/are rejected.
- 7) ☒ Claim(s) 3,4,7,8 and 10-12 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-12 are currently pending

Claim Objections

Claims 10-12 are objected to for being substantial duplicates of claim 1. When claims in an application are duplicates, or else are so close in content that they cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the others as being substantial duplicates of the allowed claim. M.P.E.P. 706.03(k). In the instant claims, it appears that the claims mentioned supra are intended to claim the method of use for the compound of formula I: as a "blood glucose-decreasing drug" (claim 10); a "lipid decreasing drug" (claim 11); and "an agonist drug of human peroxisome proliferator-activated receptor" (claim 12). This objection can be overcome by deleting the duplicate claims, or by amending the claims to be correct methods of use claims including positive method steps.

Claims 3, 4, 7 and 8 are objected to as being dependent upon a rejected base claim, but would appear allowable over the prior art of record if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

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which applicant regards as the invention, since claim 1 contains parenthetical marks, rendering each of the claims indefinite because it is unclear what exactly applicant means to claim as the invention. This rejection can be overcome by deleting the parentheses from claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,223,522 and EP 0 846 693. Also, claims 1, 2, 6 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/32863 and EP 0 846 693.

The claims at issue teach the benzylthiazolidine-2,4-dione products of the formula (1) wherein B denotes a lower alkyl, lower alkoxy, halogen, trifluoromethyl, trifluoromethoxy, phenyl, phenoxy, or benzyloxy and A denotes $-\text{CH}_2\text{CONH}-$, $-\text{NHCONH}-$, $-\text{CH}_2\text{CH}_2\text{CO}-$ or NHCOCH_2- . These products are useful for the treatment of diabetes, hyperlipidemia and as glucose lowering drugs.

Determining the scope and contents of the prior art.

US Patent No. 5,223,522 discloses thiazolidinedione compounds of the formula (I) wherein X1 and X2 can be H, methyl, CG_3 , phenyl (preferably X2 is hydrogen and X1 is 4-phenyl, 4-benzyloxy, hydrogen, or 2-methoxy). R is hydrogen or methyl, preferably hydrogen. n is 0 to 1, preferably 0. A and B are CH, X is S, SO, SO_2 , CH_2 , CHOH , CO (preferably CO), Y is CHR_1 or NR_2 , and Z is CHR_3 , or preferably CH_2CH_2 (column 4 lines 1-40). These compounds are blood glucose lowering drugs (column 4, line 65).

EP 0 846 693 discloses benzyldioxothiazolidylbenzamide compounds of the formula (I) which are useful for the treatment of diabetes and hyperlipidemia (page 2, lines 1-6). The compound of formula (I) is substituted by R1, R2 and R3. R1 and R2

can be hydrogen, lower alkyl, lower alkoxy, lower haloalkyl, etc., while R3 can be lower alkoxy, hydroxyl or halogen atom. The dotted line indicated a double or a single bond (page 2 lines 30-46). Furthermore, EP 0 846 693 discloses specific compounds wherein the dotted line is a single bond, and R3 is **methoxy** (compound examples 17 where R1 is 3-CF3, 19 where R1 is 2-CF3, 22 where R1 is 4-t-Bu and 26 where R1 is 4-MeO in Table 5, pages 12-13).

WO 97/32863 discloses thiazolidine-2,4-dione derivative compounds useful for treatment of diabetes (abstract) wherein in the compound of formula (I-a), A can be CONH or NHCO (page 4). Furthermore, WO 97/32863 discloses specific examples 3-24 on page 29 where A is CONH and R1 is substituted and unsubstituted phenyl.

Ascertaining the differences between the prior art and the claims at issue.

The differences between the prior art of US Patent No. 5223522 and the claims at issue is that the prior art compounds do not have a methoxy substituent on the benzylthiazolidine-2, 4-dione.

The difference between the prior art of EO 0 846 693 and the claims at issue is that the prior art compound has CH2NHCO in the position equivalent to substituent A on the applicants claimed formula (1).

The difference between the prior art of WO 97/32863 and the claims at issue is that the prior art compounds do not have a methoxy substituent on the benzylthiazolidine-2, 4-dione.

Resolving the level of ordinary skill in the pertinent art.

However, minus the showing of unobvious results, it would have been obvious to one of ordinary skill in the art at the time of the invention when faced with US Patent No.

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5223522 and EP 0 846 693 to create products which are useful for the treatment of diabetes and as glucose lowering drugs, wherein A is $\text{CH}_2\text{CH}_2\text{CO}$ and the benzylthiazolidine-2, 4-dione is substituted by methoxy, due to the similar chemical structure (benzylthiazolidine-2, 4-dione) of the compounds of the prior art, which is seen in the disclosure of US Patent No. 5223522 that also discloses CH_2NHCO (the substituent found on the compounds from EP 0 846 693) is a possible substituent on the compounds useful as blood glucose lowering drugs. The reasoning behind the finding of obviousness is that EP 0 846 693 discloses compounds in which the basic structure common to US Patent No. 5223522 (i.e. benzylthiazolidine-2, 4-dione) can be substituted by methoxy and is useful for the treatment of diabetes and hyperlipidemia. Consequently, the motivation to prepare compounds as found in US Patent No. 5223522 substituted by methoxy would be to create other useful benzylthiazolidine-2,4-dione compounds useful as blood glucose lowering drugs.

The same reasoning applies to WO 97/32863 and EP 0 846 693. It would have been obvious to one of ordinary skill in the art at the time of the invention to create products which are useful for the treatment of diabetes, wherein A is CH_2CONH and the benzylthiazolidine-2, 4-dione is substituted by methoxy due to the similar chemical structure (benzylthiazolidine-2, 4-dione) of the compounds of the prior art, which is seen in the disclosure of WO 97/32863 that also discloses CH_2NHCO (the substituent found on the compounds from EP 0 846 693) is a possible substituent on the compounds useful for the treatment of diabetes. The reasoning behind the finding of obviousness is that EP 0 846 693 discloses compounds in which the basic structure common to WO

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97/32863 (i.e. benzylthiazolidine-2, 4-dione) can be substituted by methoxy and is useful for the treatment of diabetes and hyperlipidemia. Consequently, the motivation to prepare compounds as found in WO 97/32863 substituted by methoxy would be to create other useful benzylthiazolidine-2, 4-dione compounds useful for the treatment of diabetes.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (703) 605-1157. Mrs. Anderson can normally be reached Monday through Friday 7:00AM to 3:30PM.

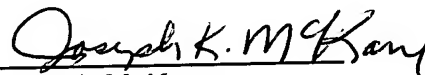
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4242, (703) 305-3592, and (703) 305-3014.



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